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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,035	10/04/2001	Daniel Albert Wettstein	1907.03	2866

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EXAMINER	
HILL, MYRON G	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/972,035	WETTSTEIN ET AL.	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) *24, 25, 27-43, and 51-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23,26,44-50 and 61-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

HC

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/6/04 has been entered.

This action is on claims 1-23, 26, 44-50, and 61-64.

Rejections Withdrawn

Claim Rejections - 35 USC § 102

The rejection of claims 1- 8, 12- 15, 17- 20, and 22 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ott is withdrawn.

The amendments to the claims make the rejection moot.

Claim Rejections - 35 USC § 103

The rejection of claims 9- 11, 16, 21, and 23 under 35 U.S.C. 103(a) as being unpatentable over Ott as applied to claims 1- 8, 12- 15, 17- 20, and 22 above, and further in view of Desai is withdrawn.

The amendments to the claims make the rejection moot

Rejections Maintained

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1- 23 and 44- 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The metes and bounds of the terms "homologue", and "fragment" are not clear.

Applicant argues that the definition of homology is clear, the the meaning of GAGp6 and TSG101 are clear and well known in the art, and has amended the claims to "contain" a late domain region and has added the phrase "capable" of interacting with (GAGp6 or TSG101). Applicant argues that "homologue", and "fragment" are clear because of the inclusion of functional language.

Applicant's arguments have been fully considered and not found persuasive.

The phrases added which include "capable" do not require that an interaction take place.

Applicant argues that "homologue", and "fragment" are clear because of the inclusion of functional language. This is not persuasive because there is not a specific region of both proteins of the pair that define the interaction.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-23, 26, 44-50, and 61-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

In the instant disclosure, the applicants have only disclosed the sequences identified as GAG (449-500) and TSG101 (7-390) (page 33, lines second and third from bottom) which are disclosed as interacting. Additionally, Table 4 shows that 3 mutants in the PTAPP region abolish interaction. No other sequences which have or comprise the

proteins were disclosed. No fragments, homologues, or regions having less than 100% identity to the disclosed sequences are shown except for the 4 mutants (3 that abolished interaction and one that did not). The specification does not set forth the metes and bounds of all sequences that comprise the GAG late domain motif, there is not enough information about it in the literature either to guide the one of ordinary skill in the art to predict the undisclosed regions where the region may encompass or if they will bind. Therefore, a written description of the other claimed sequences of GAG late domains, fragments, portions with less than 100% identity, and TSG101 fragments portions, homologues, and portions with less than 100% identity that have the claimed interaction to form a complex should be disclosed to overcome this rejection. Applicant has not disclosed any specific motif associated with TSG101 that is essential for binding except for the 200 residue N terminal portion. See also University of California v. Eli Lilly and Co., 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. 35 USC 112 requires *inter alia* that a patent specification contain a written description of the invention and the manner and process of making and using it "in such full clear and concise terms as to enable one skilled in the art ... to make and use" the invention. Case law has made it clear that the requirements for a "written description" and an "enabling disclosure" are separate. For example, where a specification contains

sufficient information to enable a skilled chemist to produce a particular compound because it gives detailed information on how to produce analogous compounds but it makes no reference to the compound in question, the "written description" requirement has not been met even though the description may be enabling.

Claims 1-23, 26, 44-50, and 61-64 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for GAGp6 (449-500) and TSG101 (7-390), does not reasonably provide enablement for all other fragments, homolgues, portions with less than 100% identity, and other GAGs or TSGs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant claims are evaluated for scope of enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The invention is drawn to an isolated protein complex. The prior art taught the late domain GAG p6 is conserved and important in viral budding. The prior art does not

teach the interaction of TSG101 and GAG. Mutations, variants, fragments, homologues, and all changes in sequences make binding and complex formation unpredictable.

The specification provides not guidance on changes in TSG101. It only provides one peptide (page 33, residues 7-390). It does not provide fragments, 50% homologies, homologues, or the like that are capable of binding to HIV GAG p6 late domain.

The specification only provides limited guidance on HIV GAGp6. Tables 3 and 4 show mutations of the PTAPP region and one mutation close by. The mutations of the PTAPP region abolish complex formation. This indicates that this region is required.

The specification also teaches that the minimum required potions for interaction are a 14 mer of HIV gag containing the late domain and residues 1-207 of TSG101 (paragraph spanning pages 34-35).

The specification has not taught how to use the invention. The specification asserts the complex or the protein parts can be used for screening assays (pages 53-61). The specification provides general teachings about screening assays. The specification does not teach any specific assays that show a novel compound can be discovered using the complex. The specification does not show that novel compounds discovered in the asserted assay will have a useful biological function. There is no showing that novel compounds discovered by using the assay will inhibit HIV budding (or some aspect of HIV infection/replication) in some meaningful way in vitro or in vivo.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Clearly there is lack of guidance directing a

skilled artisan to practice the instantly claimed invention. Without specific guidance or direction and /or working examples, one of ordinary skill in the art would not be able to make and use the entire scope of the invention as claimed, without undue experimentation.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Myron G. Hill
Patent Examiner
18 March 2005

James C. Housel 3/21/05
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